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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,073	02/21/2002	Yoichi Iimura	0425-0877P	9107
2292	7590	09/27/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 09/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,073	Applicant(s) IIMURA ET AL.	
	Examiner Brenda Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-17 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9-12, 15-17 and 21 is/are rejected.
- 7) ☒ Claim(s) 4 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12, 15-17 and 21 are pending in the application.

This action is in response to applicant's amendment filed July 20, 2004. Claims 1, 2, 6, 10-12, 16 and 17 have been amended, claims 13, 14 and 18-20 have been canceled and claim 21 is newly added.

Response to Amendment

Applicant's arguments filed July 20, 2004 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the improper Markush rejection of claims 1 and 4-20, labeled paragraph 2 of the last office action, which is hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 11-20 the applicant's amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that claims 11-15 of which claims 13 and 14 have been canceled are directed to a composition, not to a method of treating a disease. However, MPEP 2164.01(c) states: When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. Hence, claims 11, 12 and 15 are included in the rejection under 35 U.S.C. § 112, first paragraph.

With regards to claims 16, 17 and 21, the applicants' stated that claims 18-20 have been canceled and claim 21 is newly added. Claims 16, 17 and 21 are directed to the method of treating or ameliorating diseases against the inhibition of an

acetylcholinesterase. The applicants stated that an article entitled "Cholinesterase Inhibitors of Alzheimer's Disease" is attached herewith, however, it was not attached to the applicant's amendment. Additionally, it is noted that the reference was published in 2001 which is after the applicant's effective filing date and hence cannot be used to support enablement at the time of filing.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims where the disorder is an inhibitor of acetylcholinesterase. As stated in the last office action it is difficult to treat many of the disorders claimed herein. The applicants discuss the use of cholinesterase inhibitors in the treatment of Alzheimer's disease, however the use of acetylcholinesterase inhibitors have only been linked to senile dementia of the Alzheimer's type.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

Claims 11, 12, 15-17 and 21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way

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as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejections of claims 1-20, labeled paragraph 4a), b), c), d), e), f) and h) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 USC § 112, second paragraph rejections of claims 1-20, labeled paragraph 4g)

g) The applicants' stated that the Examiner's comments are not understood and are entirely without basis. However, claim 16 generically claims the method of treating a disorder responsive to the activity of acetylcholinesterase inhibition. The rejection of claims 16, 17 and 21 were on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of acetylcholinesterase inhibition. The scope of diseases and/or disorders associated with the activity of acetylcholinesterase inhibitors could alter over time. The applicants' are not entitled to preempt the efforts of others.

Claims 16, 17 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 101 rejection of claims 18-20, labeled paragraph 5 of the last office action, which is hereby **withdrawn**.

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In view of the amendment dated July 20, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 10, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 10 recites the limitation "1-benzazepin-8-yl" in the nomenclature of the 13th and 14th species. There is insufficient antecedent basis for this limitation in the claim.
- b) Claim 10 recites the limitation "1,2-benzisooxazol-6-one" in the nomenclature of the 15th and 16th species. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 10 recites the limitation "6-benzothiazolyl" in the nomenclature of the 17th and 18th species. There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 12 is a substantial duplicate of claim 11 as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

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- e) Claim 15 is a substantial duplicate of claim 11 as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 9, 11, 12, 15-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09-268176. JP 09-268176 teaches the compounds, compositions and method of use of the compounds of formula I where R⁵ is –CH₂OH, m is 1, R^{3a} and R^{3b} are methoxy, A is benzene and R⁶ is H. See the middle of column 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5-7, 9, 11, 12, 15-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 09-268176. The generic structure of JP 09-268176 encompasses the instantly claimed compounds (see Formula I, abstract) and for the same uses as claimed herein. The example in column 16 differs only in the nature of

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the A, B, n, R, m, C and D substituents of the pipeirdine compounds. The abstract defines the substituent A is formula II, B is H, hydroxyl, etc., n is 0-2, C is H or hydroxyl, D is H or a lower hydroxyalkyl, R is H, a lower alkyl or a lower alkoxy and m is 0-4. Compounds of the instant invention are generically embraced by JP 09-268176 in view of the interchange ability of the A, B, n, R, m, C and D substituents of the pipeirdine compounds. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example methyl, ethyl, propyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Claim Objections

8. Claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Applicants' attention is directed to U.S. Patent No. 20040048893, which while not competent as a reference against the instant claims, claims subject matter that is similar and/or identical to that claimed herein. Two patents cannot issue on the same subject matter, unless applicants can demonstrate that the claims are patentably distinct from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
September 24, 2004